K053111

MAY - 4 2006

DIAGNOSTICA STAGO, Inc.

Five Century Drive
Parsippany, NJ 07054
1-800-222-COAG
973-631-1200
Fax: 973-631-1618
www.stago-us.com

510K Summary

Distributor:

Diagnostica Stago, Inc.
5 Century Dr.
Parsippany, NJ 07054
(973) 631-1200-116
Fax: (973) 631-1618

For Diagnostica Stago, the French manufacturer located at:

Diagnostica Stago
9, rue des Frères Chausson
Boite Postal 226
92600 Asnières FRANCE

November 1, 2005

Trade Name: STA®-Cephascreen Kit
Common Name: APTT Kit
Classification Name: partial thromboplastin time (21 CFR 864.7925, Product code GFO)

Substantial Equivalence:

The proposed STA®-Cephascreen Kit has been compared with the predicate device STA®-C.K.Prest® kit (K792048, Diagnostica Stago France)

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I. Product Description

The STA®-Cephascreen kits provide reagents for the determination of the activated partial thromboplastin time (APTT) according to Langdell R.D. *et al.* (1) and Larrieu M. J., Weilland C. (2) by analyzers of the STA® line suitable to these reagents.

II. Explanation

The APTT is a general coagulation screening test of the intrinsic and common coagulation pathways (factors XII, XI, IX, VIII,X, V, II and fibrinogen).
A prolongation of the APTT is encountered in the following situations (7):

-Congenital Deficiencies

- If the prothrombin time (PT) is normal, the following factors may be deficient:
  - Factor VIII
  - Factor IX
  - Factor XI
  - Factor XII
- If all these factors are normal, a deficiency in HMW kininogen (Fitzgerald factor) should be considered

-Acquired Deficiencies

- Liver diseases
- Consumptive coagulopathy
- Circulating anticoagulants (antiprothrombinase or circulating anticoagulant against a factor)
- During heparin or oral anticoagulant therapy
- Treatments with thrombin inhibitors (e.g., hirudin, argatroban...)

III. Test Principle

The APTT involves the recalcification of plasma in the presence of a standardized amount of cephalin (platelet substitute) and a factor XII activator (polyphenolic component).

IV. Kit Contents

STA®-Cephascreen ®: reagent containing cephalin (platelet substitute), prepared from rabbit cerebral tissues (2) and a polyphenolic activator (patent pending) in a buffered medium.

The STA®-Cephascreen ® is available in two different kit sizes:

- STA®-Cephascreen®④ (REF00308) containing 12x4 mL vials ready for use reagent
- STA®-Cephascreen®⑩ (REF 00310) containing 12x10 mL vials of ready for use reagent

The STA®-Cephascreen® reagents are provided in liquid form, ready for use after stabilization and mixing when a vial is opened.

V. Technological Characteristics as compared to STA®-C.K. Prest®

STA®-Cephascreen ® is engineered to be a screening test, using APTT to assist and clarify diagnoses. STA®-C.K.Prest ®, while extremely similar, is geared towards testing with factors.

While the bases of the two tests are very similar, different activators are used for the activation of the PTT. The predicate device uses kaolin, while STA®-Cephascreen ® uses a polyphenolic activator.

VI. Substantial Equivalence

The proposed STA®-Cephascreen ® kits have been compared with the predicate device STA®-C.K.Prest ® (Diagnostica Stago, France K792048).

The two kits were used in parallel exactly as described by their respective package inserts to determine the activated partial thromboplastin time (APTT) in 125 plasmas comprising:

- plasmas from presumed normal individuals (n=40)
- plasmas from patients receiving unfractionated heparin (UFH) therapy (n=20)
- plasmas from patients receiving low molecular weight heparin (LMWH) therapy (n=20)
- plasmas from patients receiving oral anticoagulant (AVK) therapy (n=15)
- LA positive plasma (n=10)
- Plasmas from patients with factor VIII deficiency (F.VIII Def.) (n=10)
- Plasmas from patients with factor IX deficiency (F. IX Def.) (n=10)

The correlation of the data was as follows:

n=125
r=0.943
a=0.78
b=8.2

Based on the range of correlating data , STA®-Cephascreen ® is substantially equivalent to the predicate device STA®-C.K.Prest ® as cleared under 510(k) number K792048.

V. Kit Storage and Stability

The reagent in intact (unopened) vials remains stable until the expiration date printed on the box, when stored at 2-8°C. This stability corresponds to a duration of 15 months after the date of manufacture.

Once a vial is opened and prepared as indicated on the package insert, the reagent has demonstrated a stability of:

-7 days (REF 00308) or 10 days (REF 00310) on STA®, STA Compact® and STA-R®
-24 hours at 20 ± 5 °C
-14 days at 2-8°C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 4 2006

DIAGNOSTICA STAGO, Inc.
C/O Melissa M. Cole
Executive and Regulatory Assistant
Five Century Drive
Parsippany, New Jersey 07054

Re: k053111
Trade/Device Name: STA® CephaScreen
Regulation Number: 21 CFR 864.7925
Regulation Name: Partial Thromboplastin Time Test
Regulatory Class: Class II
Product Code: GFO
Dated: 01 May 2006
Received: 02 May 2006

Dear Ms. Cole:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PH.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053111

Device Name: STA®- CEPHASCREEN

Indications For Use:

The STA® - Cephascreen® kits provide reagents for the determination of the activated partial thromboplastin time (APTT) in citrated plasma on the STA® line of analyzers suitable to these reagents.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K053111